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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/076,622 | 02/13/2002 | Raymond L. Houghton | 210121.470C11 | 2478 |

500 7590 12/10/2004

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EXAMINER

EPPS FORD, JANET L

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1635 | |

DATE MAILED: 12/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|---------------------------|-----------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/076,622 | HOUGHTON ET AL. |
| | Examiner | Art Unit |
| | Janet L. Epps-Ford, Ph.D. | 1635 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 12 October 2004.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 11 and 13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 11 and 13 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Arguments

Claim Rejections - 35 USC § 112

2. Claim 11 and 13 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record set forth in the Official action mailed 3-11-03 (Written Description).

Applicant's arguments filed 10-12-04 were fully considered but they are not persuasive. Applicants traversed the instant rejection on the grounds that the present specification reasonably conveys that Applicants were in possession of the subject matter encompassed by the claims as amended herewith.

Applicants traversed this rejection on the grounds that all that is required to comply with the written description requirement of 35 USC § 112, 1st paragraph is that the specification reasonably convey to a person skilled in the art that, at the time of filing, the inventor had possession of the subject matter that is claimed in the application. Applicants are also reminded that the "Written Description" Requirement guidelines of January 5, 2001 (Vol. 66, No. 4, pages 1099-1111) also states that "[A]n applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as

words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was “ready for patenting” such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that applicant was in possession of the claimed invention.” As set forth in the prior Office Action, out of the broad genus of polypeptides which may have 90% identity to SEQ ID NO: 475, it is unclear how the skilled artisan, apart from further experimentation, would be able to predict which combination of modifications of SEQ ID NO: 475 that would produce a polypeptide of 90% would produce a polypeptide that is useful for producing an immune response in a patient for therapeutic purposes. Therefore, since it is apparent that further experimentation is required to identify the full scope of compounds useful in the claimed methods, it was concluded that the full scope of the claimed invention was not “ready for patenting” at the time of filing of the present application.

Applicants also argued that the specification clearly describes the B726P breast tumor antigen, and clearly describes generating cytotoxic T cell (CTL) lines and CD4+ T helper cell lines using the B726P polypeptide and fragments thereof, and furthermore describes antibody epitope mapping and sequences as set forth in Table 3, page 151 (SEQ ID NO: 597, 609, 612, 615, 617). However, the instant claims are drawn to polypeptides that have at least 90% identity with an alternatively spliced B726P polypeptide and not to the B726P polypeptide itself. Moreover, in regards to the antibody epitope sequences identified in the instant specification (See Table 3), these sequences represent 20 mer peptides that correspond to the amino acid

sequence of the down stream ORF of B726P as set forth in SEQ ID NO: 176 of the instant application. SEQ ID NO: 176 comprises 317 amino acids and is only about 30% identical to the full length sequence of SEQ ID NO: 475. Applicants have not provided any guidance as how to design compounds that are 90% identical to the full length sequence of SEQ ID NO: 475, wherein the polypeptide is useful for producing an immune response in a patient for therapeutic purposes. Although there is guidance for which 20mer peptides of SEQ ID NO: 176 may be useful for producing an immune response it is noted that the instant claims encompass polypeptides having 90% identity to SEQ ID NO: 475. Applicants are essentially suggesting that the structures of 20mer peptides corresponding to SEQ ID NO: 176 would be useful to predict the structure of polypeptides of at least about 900 amino acids in length to be used in a method for producing an immune response in a patient for therapeutic purposes. It is noted that SEQ IDNO: 176 is about 99.674 % identical to amino acids 696 through 1000, which represents only about 30% of the total polypeptide of SEQ ID NO: 475.

As stated in the prior Office Action, due to the limited structural information regarding what amino acid residues that may be deleted, substituted or inserted into the polypeptides according to the present invention, wherein said polypeptide retains at least 90% identity to the full length sequence of SEQ ID NO: 475 and maintains the ability to be used to stimulate an immune response in a patient, the level of unpredictability associated with protein structure and predicting protein function, and the lack of guidance thereof in the specification as filed, it is concluded that Applicant's disclosure is insufficient to adequately describe the genus of polypeptides encompassed by the claimed invention. Applicant's specification does not provide sufficient description for the broad genus of polypeptides encompassed by the instant claims

since providing a means to isolate a compound cannot show possession. What is required is an actual description of the claimed invention, particularly by means of drawings or structural chemical formulas that show that the invention was complete at the time of filing of the claimed invention.

The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is required. Since the disclosure fails to describe the common attributes or characteristics that identify the members of the genus, and because the genus is highly variant, the disclosed sequence of SEQ ID NO: 475, alone is not sufficient to describe claimed genus.

One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, applicant was not in possession of the claimed genus.

Conclusion

3. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford, Ph.D. whose telephone number is 571-272-0757. The examiner can normally be reached on Monday-Saturday, Flex Schedule.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on 571-272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Janet L. Epps-Ford, Ph.D.
Patent Examiner
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